IN THE DRAWINGS

Please enter the attached Formal Replacement Drawing sheets.

REMARKS

The following remarks are made in response to the Non-Final Office Action mailed August 19, 2005. In that Office Action, the Examiner objected to the drawings for a) failing to designate "Prior Art" (FIG. 2) and b) reference numerals not complying with 37 C.F.R. 1.84. The Examiner also objected to the IDS as filed and requested that a copy of the art referred to in the specification at paragraphs 0018 and 0033 be provided. Claims 16, 17, 26, 28, 29, and 32 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 32-37 were rejected under 35 U.S.C. §102(e) as being anticipated by Hoste, U.S. Patent No. 6,508,806 ("Hoste"). Claims 32-35 were rejected under 35 U.S.C. §102(b) as being anticipated by Park et al., U.S. Patent No. 6,159,187 ("Park"). Claim 38 was rejected under 35 U.S.C. §103(a) a being unpatentable over Hoste. Claims 1-10, 14, 15, and 31 were rejected under 35 U.S.C. §103(a) as being unpatentable over Park in view of Chludzinski et al., U.S. Patent No. 6,837,890 ("Chludzinski"). Claims 11-13 were rejected under 35 U.S.C. §103(a) as being unpatentable over Park in view of Chludzinski, and further in view of Samson et al., U.S. Patent No. 6,143,013 ("Samson"). Claims 16, 17, 25, 26, 28, 30, and 39 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kiemeneij, U.S. Patent No. 6,620,150 ("Kiemeneij") in view of Jafari et al., U.S. Patent No. 6,652,472 ("Jafari"). Claim 27 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kiemeneij in view of Jafari, and further in view of Chaisson et al., U.S. Patent No. 6,086,548 ("Chaisson"). The Examiner's indication that claim 29 would be allowable if rewritten to overcome the rejections under §112 is noted with appreciation.

With this Response, claims 16, 17, 25, and 31-33 have been amended; claims 3-9 cancelled; and newly presented claims 40-46 added. Claims 1, 2, 10-17 and 25-46 are pending in the application and are presented for consideration and allowance.

Formal Replacement Drawings

In response to the Examiner's comments regarding a "prior art" legend being added to FIG. 2, as well as objections to the reference numerals used in the drawings, it is respectfully

requested that the concurrently filed replacement drawing sheets be entered. It is believed that no new matter is presented, and that the replacement drawings address all objections.

IDS Requirements under 37 C.F.R. 1.105

In response to the Examiner's request, information relating to a known variable stiffness guidewire is provided in the concurrently filed Supplemental Information Disclosure Statement.

35 U.S.C. §112 Rejections

Claim 16 and 32 have been amended to address the Examiner's concerns relating to the phrase "said catheter". It is respectfully requested that the rejections of claim 16 and 32 under 35 U.S.C. §112, second paragraph, be withdrawn.

With respect to the rejections of claims 26, 28, and 29 under 35 U.S.C. §112, second paragraph, the Office Action states that "it is not clear how the step of advancing can be performed if the guidewire was previously removed in claim 25". In response, Applicant respectfully notes that claim 25 does not require or otherwise recite that the guidewire is "removed". Instead, claim 25 recites "withdrawing" the guidewire into the catheter. "Withdrawing" is in no way limited to "removing" the guidewire, such that claims 26, 28, and 29 are definite. In addition, even if "withdrawing" were viewed as being limited to "removal", claim 25 does not recite any particular order to the method limitations set forth therein. Similarly, claims 26, 28, and 29 do not require that the recited method steps occur before or after the "withdrawing" limitation of claim 25. For at least these reasons, then, it is respectfully requested that the rejections of claims 26, 28, and 29 under 35 U.S.C. §112, second paragraph, be withdrawn.

35 U.S.C. §102 Rejections

Independent claims 32 and 33 were rejected under 35 U.S.C. §102 as being anticipated by Hoste and by Park. As described in greater detail below, both Hoste and Park describe a catheter configuration in which the distal end or tip thereof has a uniform flexibility. In contrast,

amended claims 32, and 33 recite, amongst other things, a catheter having a distal tip characterized by a varying flexibility.

For example, Hoste describes a catheter 10 including a catheter shaft 11. FIG. 1 of Hoste depicts a distal section 13 of the shaft 11 as forming a curve. To this end, Hoste describes that the J-shape of the distal section 13 reflects the well-known Judkins or Amplatz configuration. (Hoste, col. 4, ll. 13-25). That is to say, Hoste teaches a pre-determined, "known" curvature for the catheter shaft 11, with this curvature coinciding with a specific, known procedure. As such, in order to properly perform the known procedure, Hoste must envision that the curvature will not change during the procedure. In fact, Hoste describes a catheter shaft wall construction 20 (including, for example, a liner 22, an inner wound layer 17, an outer wound layer 18, and a jacket 19) that is highly rigid to facilitate torque transmission and collapse performance. (Hoste, col. 3, ll. 54-57; col. 4, ll. 36-60). In the illustrated and described embodiments of Hoste, the above-mentioned catheter shaft wall construction 20 appears to extend along an entirety of the catheter shaft 11; nothing in Hoste teaches or suggests to the contrary. Thus, the curved distal portion 13 inherently must have a uniform or unmodulated flexibility. In fact, because the curved shape of Hoste is specifically selected to perform a particular procedure, it follows that a flexibility of the Hoste catheter shaft 11 must be uniform to ensure the desired shape is consistently achieved and maintained.

Similarly, Park describes a catheter 110, a section of which self-forms to a selected shape upon application of heat and retains that shape upon cooling and with any re-heating. (Park, Abstract). To this end, Park describes use of a woven braid 206 formed of a nickel-titanium (or similar) material that, upon heating, effectuates a transition from a first shape to a pre-set, second shape. Regardless of how "flexible" the woven braid construction is in either the first or second shape, this flexibility is clearly uniform (for example, along the distal section of 112 of FIG. 2). In fact, FIG. 2 of Park illustrates the distal portion 112 in the pre-set, curved state with a guidewire 124 extending therethrough. Clearly, the guidewire 124 does not affect a curvature of the distal section 112. Thus, the Park catheter is not characterized by a distal tip having a varying flexibility.

In contrast to the above, amended claim 32 recites a catheter including a distal tip having a pre-determined curvature in a natural state and characterized by a varying flexibility adapted to permit incremental bending of the distal tip by advancing a variable stiffness guidewire therethrough. The uniform wall construction 20 of Hoste by necessity imparts a uniform flexibility onto the curved distal portion 13. Similarly, the distal section 112 of Park is also characterized by uniform flexibility. In fact, FIG. 2 of Park clearly teaches that the distal tip thereof is not adapted to permit incremental bending via advancement of the guidewire 124 therethrough. As such, amended claim 32 is not taught or suggested by Hoste or Park.

Similarly, amended claim 33 recites a catheter having a distal tip characterized by a varying flexibility along a length thereof and defining a curved shape. Again, Hoste and Park do not teach or suggest at least these limitations. As such, claim 33, as well as claims 1, 2, 10-15, and 34-38 depending therefrom, are allowable over the cited references.

35 U.S.C. §103 Rejections

Claim 31 was rejected over Park in view of Chludzinski. As amended, claim 31 recites a catheter including a distal section having a pre-formed curved portion exhibiting varying flexibility along a length thereof. As described above, Park does not teach or suggest at least this limitation; to the contrary, FIG. 2 of Park makes clear that the curved distal portion 112 is uniformly rigid to the point that the curved shape will not change in the presence of the guidewire 124 passing therethrough. Modifying Park to include the differing bend radius of curvature set forth in Chludzinski does not alter this inherent limitation. Thus, for at least these reasons, it is respectfully requested that the rejection of claim 31 be withdrawn.

Independent claim 16 was rejected under 35 U.S.C. §103(a) as being unpatentable over Kiemeneij in view of Jafari. As amended, claim 16 recites a catheter in combination with a variable stiffness guidewire. To this end, the catheter of amended claim 16 has a curved distal tip characterized by a pre-formed curved portion and having a flexibility to permit straightening of the curved distal tip by sliding the guidewire relative to the catheter. In contrast, it is respectfully submitted that Kiemeneij describes a catheter specifically configured for use without a guidewire. More particularly, Kiemeneij teaches a catheter having a series of specific bends

and shaft flexibilities that allows selective cannulation of right and left coronary arteries and venous by-pass graphs. The catheter shaft configuration is designed to rely upon support provided by the human anatomy during use to effectuate a desired distal end positioning. (Kiemeneij, col. 3, ll. 54-67). As a result, Kiemeneij specifically teaches that "there is no need for a guidewire to bring the tip of the catheter in the direction of the origin of the coronary, prior to cannulation." (Kiemeneij, col. 4, ll. 4-6). Thus, Kiemeneij teaches away from a combination catheter and guidewire as otherwise set forth in amended claim 16. For at least these same reasons, then, a requisite suggestion to combine the Kiemeneij catheter with the variable stiffness guidewire of Jafari cannot exist. As such, it is respectfully submitted that amended claim 16, as well as claim 17 depending therefrom, is allowable over the cited references.

Claim 39 was similarly rejected under 35 U.S.C. §103(a) as being obvious over Kiemeneij in view of Jafari. As described above, Kiemeneij specifically seeks to eliminate the use of a guidewire in locating a branch body passage. To the contrary, FIGS. 3-6 of Kiemeneij (in conjunction with the related specification language) makes clear that a guidewire is not employed; instead, a portion of the catheter is support against an anatomical feature of the patient, with the catheter being pushed or pulled to effectuate desired positioning of the distal end. In light of the fact that Kiemeneij teaches away from the use of a guidewire, a requisite suggestion to combine Kiemeneij with the variable stiffness guidewire of Jafari does not exist; even if it did, the corresponding method limitations of claim 39 are not taught or suggested. Further, it is noted that the catheterization techniques described in Kiemeneij all relate to primary or large bodily passages (e.g., right and left coronary arteries). Thus, Kiemeneij does not teach or suggest targeting a branch body passage having a diameter of not more than 4 mm as otherwise set forth in claim 39. For at least these reasons, then, it is respectfully submitted that claim 39 is allowable over the cited references.

Newly presented claims 40-44 depend, in one form or another, from claim 32. Support for the language of claims 40-44 is found, for example, at pg. 9, para. 33 and in originally-presented claims 3-9. As previously described, claim 32 is allowable over the cited references. As such, claims 40-44 are similarly allowable. Further, each of claims 40-44 recites additionally allowable subject matter.

For example, newly presented claim 40 recites that the distal tip includes a first subsection extending from a distal-most end of the catheter and a pre-formed curved subsection extending immediately proximal from the first straight subsection. Further, a bending stiffness of the first straight subsection differs from that of the pre-formed curved subsection. As previously described, the flexibility or bending stiffness associated with Hoste and Park is uniform along the distal tip portion thereof. Similarly, Kiemeneij (col. 5, ll. 38-40) describes that the distal straight portion 10 and the first primary curve 3 has a consistent flexibility (relative to a stiffness associated with the catheter portions immediately proximal thereof). Thus, newly presented claim 40 recites additionally allowable subject matter.

Newly presented claim 41 depends from claim 40 and recites that the bending stiffness of the first straight subsection is greater than the bending stiffness of the pre-formed curved subsection. None of the cited references teach or otherwise suggest this limitation. As such, claim 41 recites additionally allowable subject matter.

Newly presented claim 42 depends from claim 40 and recites a second straight subsection extending immediately proximal from the pre-formed curved subsection and having a bending stiffness differing from that of the pre-formed curved subsection. Once again, each of Hoste and Park inherently have a uniform flexibility or bending stiffness along the distal tip thereof. Further, the distal portion 15 of the second straight portion 12 of Kiemeneij has a flexibility or bending stiffness similar to that of the curved section 3. (Kiemeneij, col. 5, ll. 38-40). As such, it is respectfully submitted that newly presented claim 42 recites additionally allowable subject matter.

Newly presented claim 43 depends from claim 42 and recites that the bending stiffness of the second straight subsection is greater than that of the pre-formed curved subsection. For at least the reasons previously described, none of the cited references teach or otherwise suggest this limitation. As such, claim 43 recites additionally allowable subject matter.

Newly presented claim 44 depends from claim 43 and recites that the bending stiffness of the first straight subsection (as well as that of the second straight subsection) is greater than that of the pre-formed curved subsection. For at least the reasons previously described, it is

respectfully submitted that none of the cited references teach or otherwise suggest this limitations. Thus, claim 44 recites additionally allowable subject matter.

Newly presented claim 45 depends from claim 39 and recites that relative to the method of claim 39, the guidewire and the guide catheter are manipulated relative to one another to change an effective curvature of the distal tip portion until the distal end faces the branch body passage. Support for this language is found, for example, at pg. 9, para. 34 and pg. 10, para 39. As described above, the method taught by Kiemeneij specifically excludes the use of a guidewire. Further, nothing in Kiemeneij teaches or suggests manipulation of a guidewire and a guide catheter relative to one another to change an effective curvature of the distal tip portion. To the contrary, Kiemeneij relies upon supporting the catheter against an anatomical feature of the patient to effectuate a desired bend position. As such, it is respectfully submitted that claim 45 recites additionally allowable subject matter.

Finally, newly presented claim 46 depends from claim 45 and recites that the distal tip portion has a pre-determined curvature in a natural state, and further that the effective curvature achieved by manipulating the guidewire and the guide catheter relative to one another is between the pre-determined curvature and a straightened state. Nothing in Kiemeneij, alone or combination with other references, teaches or suggests this limitation. As such, it is respectfully submitted that newly presented claim 46 recites additionally allowable subject matter.

CONCLUSION

In view of the above, Applicant respectfully submits that pending claims 1, 2, 10-17 and 25-46 are in form for allowance and are not taught or suggested by the cited references. Therefore, reconsideration and withdrawal of the rejections and allowance of claims 1, 2, 10-17 and 25-46 is respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 50-0471.

The Examiner is invited to contact the Applicant's representative at the below-listed telephone numbers to facilitate prosecution of this application.

Any inquiry regarding this Amendment and Response should be directed to Timothy A. Czaja at Telephone No. (612) 573-2004, Facsimile No. (612) 573-2005. In addition, all correspondence should continue to be directed to the following address:

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CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 14th day of **December, 2005**.

By: _____
Name: **Timothy A. Czaja**